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EXAMINER

KRUSE, DAVID H

ART UNIT PAPER NUMBER

1638

DATE MAILED: 06/03/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/759,704

Applicant(s)

SWANSON, BRIAN DOUGLAS

Examiner

David H Kruse

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-10,15,16,21,23-27,37-43 and 50-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,2,4-8,21,23-27 and 40 is/are allowed.
- 6) ☒ Claim(s) 9,10,15,16,37-39, 41-43 and 50-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

STATUS OF THE APPLICATION

1. This Office action is in response to Applicant's amendments and remarks filed 24 March 2003.
2. Claims 3, 11-14, 17-20, 22, 28-36, 44 and 47-49 have been cancelled as indicated in the response and new claims 50-57 have been entered as requested.
3. Those rejections not specifically addressed in this Office action are withdrawn in view of Applicant's amendments and/or arguments.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Specification

5. The amendment filed 24 March 2003 is objected to under 35 U.S.C. § 132 because it introduces new matter into the disclosure. 35 U.S.C. § 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: Table A comprising SSR data, inserted on page 16 of the specification at line 23.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Objections

6. Claims 51 and 55 are objected to under 37 CFR § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The instant

claims are directed to products, wherein said claims fail to further limit the method claim upon which they depend. Appropriate correction is required.

7. Claims 9 and 53 is objected to for a minor informality, wherein said claims are directed to a product by process, and the process does not recite a specific, produced product. Claim 9 should read -- A first generation --. Claim 53 should read -- A first generation hybrid maize plant --.

Claim Rejections - 35 USC § 112

8. Claims 51 and 55-57 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 51 and 55 are rejected as indefinite for being in improper Markush format. The Office recommends the use of the phrase "selected from the group consisting of..." with the use of the conjunction "and" rather than "or" in listing the species. See MPEP 2173.05(h). Claims 56 and 57 are also indefinite because said claims do not obviate the indefiniteness of claim 55.

9. Claims 43 and 50-53 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 43 recites "at least 50% genetic contribution from". Claims 50-52 and dependents recite "backcross conversion"

maize plants. There is no basis in the specification for either term. Accordingly, these terms constitute NEW MATTER.

10. Claims 9, 10, 15, 16, 37- 39, 41-43 remain rejected and new claims 50-54 and 57 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 23 December 2002. Applicant's arguments filed 24 March 2003 have been fully considered but they are not persuasive.

Applicant argues that possession is shown via Tables 3 and 4A-4C and by the fact that a seed deposit is made and F1 plants made with PH6WG as a parent will contain all of the homozygous alleles of PH6WG. Applicant also argues that F1 hybrid seed and plant produced using PH6WG, regardless of the other maize plant used, is identifiable because it will have one set of alleles coming from PH6WG, and that one of ordinary skill in the art would be able to run a molecular profile on PH6WG and the F1 hybrid and be able to identify the F1 hybrid as being produced from PH6WG (page 18 of the Remarks). This argument is not found to be persuasive because Applicant does not describe how to identify F1 hybrid maize plants produced from the exemplified PH6WG inbred maize plant. Applicant states that isozymes and RFLPs are the most widely used molecular markers on page 16 of the specification, but no detailed methodology is

provided regarding the use of any molecular marker techniques, particularly the SSR markers utilized in the Bhatramakki, Rule 132 declaration submitted 24 March 2003.

As directed to transgenic "conversion" plants, Applicant argues that the claims include the well known method of producing backcross and transgenic conversion plants and that the product by process claims are further limited by specified conversion or transgenic traits (page 14 of the Remarks). This argument is not found to be persuasive because those rejected claims directed to transgenic maize plants do not specify what transgene is introduced, or how any transgene affects the exemplified inbred maize plant.

Applicant argues that examples of transgenes, genes and traits that can be backcrossed into the PH6WG are given in the application. Applicant also argues that breeders, by using molecular markers, may obtain up to 98% genome identity between the backcross conversion and the recurrent parent after two backcrosses (page 14, 2nd paragraph of the Remarks). Applicant cites Openshaw *et al* 1994 (Proceedings Symposium of the Analysis of Molecular Data, August 1994, pp. 41-43. Crop Science Society of America, Corvallis, OR). This argument is not found to be persuasive. The Examiner has reviewed Openshaw, which states on page 41, left column, that the method can be used wherein "a line is obtained that is essentially a version of the RP(recurrent parent) that included the introgressed allele"; Openshaw does not state that the starting "elite genotype" is reproduced having only the introgressed allele(s).

Applicant argues that inbred PH6WGH transformed to comprise a transgene is also easily identifiable through the use of molecular markers and that a transgenic

version of PH6WG would have the same molecular profile as PH6WG with the possible exception of a marker used in the profile that is located at the site of transgene insertion (page 14, 2nd paragraph of the Remarks). This argument is not found to be persuasive because, one of skill in the art would have to know what transgene to look for and what molecular markers would identify inbred PH6WG from any other inbred maize plant.

Applicant argues that the method of backcrossing genes into an inbred maize plant is well known and well understood to one of ordinary skill in the art and that the art states that a backcross-derived inbred line fits into the same hybrid combination as the recurrent parent inbred line and contributes the effect of the additional gene through the backcross (page 15 of the Remarks). This argument is not found to be persuasive because as directed to products of a backcross conversion inbred it is unclear from the instant specification that a deposit of the exemplified PH6WG adequately describes the genus of backcross conversion inbred plants as broadly claimed. In addition, Applicant provides limited guidance on what "traits" are to be backcrossed into the exemplified inbred plant that would be encompassed by claim 51 or 53, or what second maize plant and what "trait" is backcrossed in the method of claim 50 or 52.

Applicant argues that as the result of the repeated use of the recurrent parent, the backcross conversion has many genetic alleles in common with the recurrent parent and that genetic analysis may be used as a means of identifying the backcross conversion. The Rule 132 Declaration by Dr. Stephen Smith labeled as Appendix C has been considered, and Applicant argues that said declaration explains how genetic analysis was used to identify backcross conversion inbreds of the exemplified PH6WG

(paragraph spanning pages 15-16 of the Remarks). This argument is not found to be persuasive because Applicant does not adequately describe a method required to identify such backcross conversion maize plants. In addition, the introduction of marker information in Table A, not originally presented, has been determined to encompass new matter and does not obviate this rejection.

Applicant argues that the method of searching for inbred PH6WG seed within a bag of hybrid seed encompassed by claims 37-39 have been adequately described (page 16, 2nd paragraph of the Remarks). This argument is not found to be persuasive because the starting material of the claimed process encompasses undefined hybrid seed, hence the process is not adequately described.

As directed to claim 15, 16, 40 and 42, Applicant argues that anyone of skill in the art would know how to utilize the well-established breeding methods with PH6WG (pages 16, 3rd paragraph to page 17 of the Remarks). This argument is not found to be persuasive because claims 15, 16 and 42 are directed to methods of maize plant breeding over an undefined number of generations, for example recurrent selection or pedigree breeding, using parental plants and progeny plant that have not been adequately described. The rejection of claim 40 is withdrawn in view of Applicant's amendment.

11. Claims 9, 10, 15, 16, 37- 39, 41-43 remain rejected and new claims 50-54 and 57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it

pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 23 December 2002. Applicant's arguments filed 24 March 2003 have been fully considered but they are not persuasive.

Applicant argues that lines 8-23 on page 16 of the specification teaches that the seed deposit allows one of ordinary skill to run a molecular profile of PH6WG and that one of ordinary skill in the art would know how to obtain markers useful for such a profile (page 18, 4th paragraph of the Remarks). This argument is not found to be persuasive because it is Applicant's burden to enable the claims, not one of skill in the art.

Regarding the amendment of the instant specification to introduce SSR fingerprint data, the Examiner maintains that such an amendment is NEW MATTER, and that *Marsili* is not controlling, as different fact patterns are involved. On page 905 of *Marsili*, penultimate paragraph, the Court states that the amendment in *Marsili* was not new matter because it merely constituted a *correction* of a *previously submitted* description of a compound, which is permissible; rather than "the question of *adding* characteristics not previously mentioned" [emphasis in the original], which remains impermissible per *Ex parte Fox* and *Ex parte Davisson & Finlay* cited by the Examiner in *Marsili*. In *Marsali*, the specification already disclosed a chemical structure of the claimed chemical compound, while the amendment merely corrected an error in the structure. In the instant application, no molecular data of any kind was presented, much

less any SSR data, so that the amendment to subsequently introduce them constitutes the impermissible addition of “characteristics not previously mentioned”.

Applicant argues that Hunsperger *et al*, cited in the previous Office action, merely discusses the level of the expression of that gene (dwarfism) differed in petunia plants of different genetic backgrounds and that Hunsperger *et al* support the fact that one can introgress a specific trait into a recurrent parent through backcross conversion (paragraph spanning pages 19-20 of the Remarks). This argument is not found to be persuasive because claims 50-53, encompass any “trait” or traits that are controlled by multiple genes, such as insect and disease resistance. Applicant’s reference to Hallauer *et al* 1988 teaching that the backcross method is effective and relatively easy to manage is noted (page 20, 1st paragraph of the Remarks). Hallauer does not obviate this rejection because methods of backcrossing do not reproduce the starting plant without undue trial and error experimentation. Given the large number of genes and traits in a maize plant, one of skill in the art could not have determined that only a single gene or traits had been introduced by said methods without undue trial and error experimentation.

Applicant argues that Kraft makes no mention of a plant comprising a single gene conversion or the use of backcrossing and that Kraft relates to linkage disequilibrium and fingerprinting in sugar beat, a crop other than maize (page 20, 2nd paragraph of the Remarks). This argument is not found to be persuasive because Kraft teaches the general knowledge of one of skill in the art at the time of Applicant’s invention as related to moving traits from a parental plant to progeny plants. In addition, Kraft teaches that

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using markers to follow traits can be unpredictable unless the marker is tightly linked to the trait. In the instant case, Applicant provides limited guidance to overcome such unpredictability.

Applicant argues that as determined by the UPOV Convention, essentially derived varieties may be obtained for example by selection of a natural or induced mutant, or of a somoclonal variant, the selection of a variant individual for plants of the initial variety, backcrossing [emphasis added], or transformation [emphasis added] by genetic engineering (paragraph spanning pages 20-21 of the Remarks). The Examiner maintains that the issue at hand is the enablement of claims under 35 USC 112, first paragraph, for which a U.S. patent is sought under 35 USC 101, rather than an application for a plant variety protection certificate or equivalent under UPOV.

Applicant's arguments concerning the teachings of Eshed *et al* appear convincing (page 21, 3rd paragraph of the Remarks).

Applicant argues that at claim 37-39, the method is clearly described in the specification on pages 5, line 21 through line 7 on page 6 and that one of ordinary skill in the art can practice such a method without undue experimentation (page 22, 2nd paragraph). This argument is not found to be persuasive because the Applicant has not adequately taught how to make and use the starting material required to practice the claimed process.

Applicant argues that at claim 50-53, that the specification, IDS references, and the seed organization of UPOV all state that backcrossing a trait into an inbred maize plant is routine practice (page 22, last paragraph of the Remarks). This argument is not

found to be persuasive because without knowing what "trait" is ingressed, and how to distinguish a "backcross conversion" of PH5WG comprising a single "trait", the claimed method would require undue trial and error experimentation, because without extensive guidance, one of skill in the art could not determine that inbred maize plant PH6WG had been reproduced only comprising a single ingressed trait.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR § 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Claims 1, 2, 4-8, 21, 23-27 and 40 are allowed.

14. Claims 9, 10, 15, 16, 37-39, 41-43 and 50-57 are rejected.

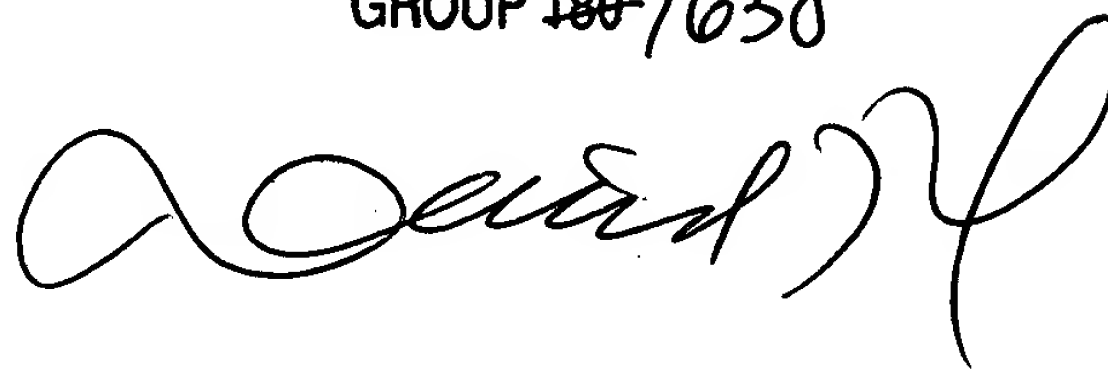
15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (703) 306-3218. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (703) 308-0196.

David H. Kruse, Ph.D.
30 May 2003

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~/1638

A handwritten signature in black ink, appearing to read "David T. Fox", written over the printed name and title.